

that the amendments should not result in new grounds for rejection as the original application discloses that the aqueous coating composition is unequivocally homogeneous. The aqueous composition is described on page 4 at lines 23-26 as being comprised of water, a water-soluble compound and a water-soluble oligomer. Thus, all the components when combined unavoidably form a **homogeneous aqueous solution**. The Examiner correctly opines that the addition of a pigment or dye to Applicants' aqueous composition would create a dispersion and not an aqueous homogeneous composition. Such a composition is more properly referred to by Applicants as a printing ink composition. The claims have been amended to reflect this distinction.

Applicants renew their request that the finality of the Office Action be withdrawn, as discussed below.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE"

Objection Under 35 U.S.C. 132  
to Amendment Filed September 26, 2001

In the Office Action and the Advisory Action, the Amendment filed by Applicants on September 26, 2001 is objected to as allegedly introducing new matter. Specifically, the Examiner indicates that the term "in a single step", appearing at page 3, lines 1-7 and 17-24; and the term "once", appearing at page 3, lines 8-16, both employed by Applicants to describe Applicants' curing method,

are not supported by the original disclosure. The Examiner requests cancellation of this alleged new matter.

In the instant reply, Applicants have withdrawn these terms used to describe Applicants' curing method. The phrase "homogeneous" has been adopted to describe the actinic radiation curable aqueous composition. This amendment does not constitute new matter as it is fully supported by the original disclosure at page 4, lines 23-26.

Therefore, the objection is moot.

Rejection Under 35 U.S.C. 112, first paragraph

Claims 1 – 49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. In particular, the Examiner indicates that the recitation in Claims 1 and 48 "in a single step", and "once" in Claim 27, used to describe Applicants' curing method and composition, are not supported by the original disclosure.

Claims 1, 27, and 48 have all been amended by deleting the rejected phrases and adding the phrase "homogeneous" to describe Applicants' actinic radiation curable aqueous composition. This phrase is fully supported by the original disclosure at page 4 at lines 23-26. Applicants respectfully request the Examiner withdraw the rejection.

The Invention

The invention is a method for producing a low-extractable film by providing an actinic radiation curable homogeneous aqueous composition, comprised of a water soluble oligomer and water, applying it to a surface and irradiating the surface with actinic radiation to form a cured film having an extraction of less than 50 ppb of uncured residue when it immersed and heated in 10 ml of a simulant liquid per square inch of cured film. The invention is also an improved actinic radiation curable homogeneous composition as described above and finally an improved printing ink composition containing the actinic radiation curable homogeneous aqueous composition described above.

Rejection Under 35 U.S.C. 102

Claims 1-19, 27-42 and 49-50 are rejected under 35 U.S.C. 102 (b) as being anticipated by U.S. Patent No. 4,287,039 to Buethe et al. (hereinafter referred to as "Buethe et al."). Claims 1-19, 27-42, 44 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,011,078 to Reich et al. (hereinafter referred to as "Reich et al.").

Buethe et al.

In particular, the Examiner states that Buethe et al. discloses a radiation curable aqueous composition comprising water and a radiation curable compound containing at least one alpha, beta ethylenically unsaturated radiation polymerizable group which may be irradiated with actinic radiation such as ultraviolet or electron beam radiation in a single step, to form a cured coated

substrate which could be utilized for coating foodstuff containers due to their low toxicity in comparison to conventional radiation curable finishes, and wherein the coating has a viscosity within the instantly claimed range, and may further contain pigments, dyes, or other filler materials.

Applicants respectfully disagree with the Examiner's characterization of the Buethe et al. composition as being anticipatory of Applicants' method for producing a low-extractable film and improved actinic radiation curable homogeneous aqueous composition.

Buethe et al. disclose an aqueous dispersion, wherein according to Buethe et al. particles of one substance (the prepolymer (B)) are uniformly dispersed in another (the water (A)). Accordingly, Buethe et al. require the presence of at least one dispersant to disperse the prepolymer (B) in the water.

By contrast, Applicants' method requires the use a homogeneous aqueous composition and does not require a dispersant. This is because Applicants employ water and a water soluble compound containing at least one alpha, beta-ethylenically unsaturated, actinic radiation polymerizable group. These components of Applicants' actinic radiation polymerizable/curable homogeneous aqueous composition forms a homogeneous solution and not a dispersion as in Buethe et al.

In addition, the Examiner states that the cured coating layer taught by Buethe et al. would "inherently" have an uncured residue amount within the instantly claimed range of less than 50 ppb. Applicants respectfully disagree and point out that the mere mention that the radiation curable coating of Buethe

et al. "can even conceivably be used for coating foodstuff containers" is certainly not enough to support the statement that the uncured residue amount would be less than 50 ppb as required by the FDA for use inside containers and in direct contact with food. See, column 6, lines 33-36; emphasis added. No where in Buethe et al. is coating of direct contact food stuff containers mentioned and thus the inherency is not supported anywhere in the patent.

Further, the cross-linking/curing of the dispersion in Buethe et al. "is carried out after the water has evaporated completely." See, column 2, lines 54-56. Conversely, the curing of Applicants' actinic radiation homogeneous aqueous composition cures in the presence of water and does not require complete evaporation of water before curing can occur.

Accordingly, Buethe et al. fails to disclose all of the features of Applicants' method for providing a low-extractable film and an improved actinic radiation curable homogeneous aqueous composition. The rejection should be withdrawn.  
Reich et al.

The Examiner further opines that Reich et al. disclose an aqueous radiation curable coating composition comprising a water soluble radiation curable compound, S, comprising at least one alpha, beta-ethylenically unsaturated radiation polymerizable double bond with at least 10 wt% water which would inherently have a viscosity within the instantly claimed range, and wherein the coating composition may further comprise pigments or other suitable additives and may be used to coat various substrates such as plastics, metals, and paper. The Examiner further states that Reich et al. disclose that their

composition may be applied to a substrate and irradiated with ultraviolet or electron beam radiation without a physical drying step.

Applicants note that Reich et al. disclose an aqueous binder dispersion containing: (a) at least one water dispersible polymer P comprising at least one alpha, beta-ethylenically unsaturated, radiation-polymerizable double bond, (b) at least one radiation-curable compound S which is different from P and which is soluble in water or is dilutable with at least 10 wt. % of water, and which comprises at least one alpha, beta-ethylenically unsaturated, radiation-polymerizable double bond, (c) a photoinitiator, (d) a filter, (e) further additives, and (F) water. Thus, the composition of Reich et al. is an aqueous dispersion requiring at least one dispersant to disperse the polymer P in the water.

In contrast, Applicants' method requires a homogeneous aqueous composition and does not require a dispersant. This is because the compound containing at least one alpha, beta-ethylenically unsaturated, radiation polymerizable group is water soluble. These components of the actinic radiation curable homogeneous aqueous composition create a homogeneous solution when combined with each other and do not form a dispersion as in Reich et al.

In addition, the Examiner states that the cured coating layer taught by Reich et al. would "inherently" have an uncured residue amount within the instantly claimed range of less than 50 ppb. Applicants respectfully disagree and submit that Reich et al. never even mention that its aqueous radiation curable dispersion is suitable for coating food stuff container. Furthermore, there is no

support for the proposition that uncured residue would be less than 50 ppb as required by the FDA for use in containers in direct contact with food.

Accordingly, Reich et al. fail to disclose all of the features of Applicants' method for providing a low-extractable film and improved actinic radiation curable homogeneous aqueous composition. The rejection should be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 20-26 and 43-47 have been rejected as being unpatentable over Buethe et al. under 35 U.S.C. 103(a). The Examiner opines that Buethe et al. teaches Applicants' invention, despite, failing to specifically teach the use of polyolefin substrates only plastics, metal and paper. Further, the Examiner states that the extractable amounts cited in Applicants claims are well known in the food packaging art and hence, would have been obvious to one having ordinary skill in the art to utilize any standard measuring process to determine the extractable amount for health related reasons of the coated substrate taught by Buethe et al. when utilized as a food container.

In addition, Claims 10, 43-44, and 50 are rejected as being unpatentable over Reich et al. under 35 U.S.C. 103(a). The Examiner opines that Reich et al. teaches Applicants' invention, despite, failing to specifically teach the precise viscosity of the coating composition nor the use of a plastic or metal substrate material.

Finally, Claims 17-26, 43-47 and 50 are rejected as being unpatentable in view of Reich et al. in further view of Buethe et al., under 35 U.S.C. 103(a). The Examiner opines that the combined prior art teaches Applicants' invention,

despite, failing to specifically teach an aqueous coating composition applied to a variety of substrates including plastics, paper, and metals and irradiated with electron beam or ultraviolet radiation to produce curd films absent any unreacted monomer, wherein Buethe et al. teaches that the aqueous coating "can even conceivably be used for coating foodstuff containers."

Buethe et al.

Applicants recognize that the surfaces/substrates claimed in their dependent claims are not novel and that the measuring protocol used to determine the uncured residue on a surface is also not novel. However, Applicants' method of producing a low-extractable film applied onto the surface/substrate such that the film has an uncured residue of less than 50 ppb and the improved actinic radiation curable homogeneous aqueous composition are novel and non-obvious in view of Buethe et al.

As discussed in the response to the 102 rejection above, Buethe et al. teaches an aqueous **dispersion** wherein the prepolymer (B) is uniformly dispersed in the water (A), but not soluble therein. Accordingly, the Buethe et al. composition requires at least one **dispersant** in order to disperse the prepolymer in the water and does not teach or suggest Applicants' actinic radiation curable homogeneous aqueous composition. Thus, Applicants' low extractable film produced from an actinic radiation curable homogeneous aqueous composition, applied to any type of surface/substrate, is not taught or even suggested by Buethe et al.

In fact, Buethe et al. teach away from Applicants' invention as it calls for the use of one component, "C", being either a **colloid or emulsifier** which is used to stabilize the dispersion. This is in direct contrast to Applicants' actinic radiation curable homogeneous aqueous composition which one of ordinary skill in the art would not consider to be a colloid or emulsifier. Thus, Buethe et al. do not teach or suggest Applicants' invention and in fact, as described above, teach away from same.

Accordingly, Applicants' method of producing a low-extractable film and improved actinic radiation curable homogeneous aqueous composition are not obvious in view of Buethe et al.

Reich et al.

Once again, Applicants recognize that the surfaces/substrates claimed in their dependent claims are not novel. Applicants do, however, disagree with the Examiner's opinion that Reich et al. teach the Applicants' range of viscosity of the coating composition.

As discussed in the response to the 102 rejection above, Reich et al. disclose an aqueous **binder dispersion** wherein a dispersant is required to disperse the polymer P in the water. Thus, Reich et al. do not teach or even suggest Applicants' method for producing a low-extractable film or improved actinic radiation curable homogeneous aqueous composition.

Further, Reich et al. in fact teach away from Applicants' invention since one of the required components "P" is an emulsifier or colloid which is stabilize the dispersion. This is in direct contrast to Applicants' actinic radiation curable

homogeneous aqueous composition which one of ordinary skill in the art would not consider to requiring a colloid or emulsifier. Thus, Reich et al. do not teach or even suggest Applicants' invention and indeed teach away from same.

Moreover, Reich et al. also teach away from Applicants' viscosity levels. Reich et al '039 disclose a **two phase dispersion system** wherein water removal is necessary to coalesce the dispersed phase and to form a continuous film. The curing of this film is inhibited by oxygen and lacks mobility. This results in an uncured composition that has high viscosity and molecular weight. By contrast, Applicants' method requires a composition having a viscosity when combined with the water solution which is very low and typically less than 300 cps, and a molecular weight of less than 1000, and in most cases under 500. Thus, Reich et al. do not teach or suggest the viscosity levels of the composition viscosity employed in Applicants' invention.

Reich et al. in view of Buethe et al.

Once again, Applicants recognize that the surfaces/substrates claimed are not novel nor is the measuring process used in order to ascertain the level of uncured residue remaining after radiation novel. However, the underlying invention is not taught or even suggested by Reich et al. in view of Buethe et al.

As previously discussed, Reich et al. and Buethe et al. both teach how to make **dispersions**, not a method for producing a low extractable film from an actinic radiation curable homogeneous aqueous composition. Thus, the combination of Reich et al. and Buethe et al. does not teach or suggest Applicants' invention.

Further, it is important to note that neither Reich et al. nor Buethe et al. ever suggest that their compositions would meet the specific Food and Drug Administration ("FDA") requirements necessary for food containers to be used in direct contact with food stuffs. Indeed, this physical attribute is actually met by Applicants' actinic radiation curable homogeneous aqueous composition. Buethe et al. simply mention that their aqueous compositions "can even conceivably be used for coating foodstuff containers", the disclosure is vacant of any proof or illustration that they are regulatory compliant. In fact, the dispersion taught in Buethe et al. could not meet the 50 ppb FDA requirement. The Buethe et al. dispersion is a **two phase system wherein water removal is necessary to** coalesce the dispersed phase and to form continuous film. The cure of this film is thus inhibited by oxygen and lacks mobility and would result in a composition of high viscosity and molecular weight, which in the case of Buethe et al. is not less than 600 cps, preferably 1000 cps. Accordingly, a Buethe et al. coating composition would have **poor cure on the surface (oxygen inhibition)** and lack the mobility required for efficient polymerization and therefore would **not be completely cured with an extractable residue of less than 50 ppb as required by the FDA.**

Additionally, the combined references teach dispersions that have a large amount of stabilizers and other surfactants that would result in a very high level of extractable residue because the additives do not react to become a part of the polymeric network. The level of extractable residual components taught by the combined references would reach 1000 to 10,000 ppm (1,000,000 ppb to

10,000,000 ppb) based on the use of 0.1% to 1% of emulsifier. This level of extractables is miles away from the 50 ppb FDA requirement. For example, in Buethe et al., the level of emulsifier used is between 3 and 12%. This would result in a level of extractable residue in the **30,000,000 ppb to 120,000,000 ppb** range. Further, Reich et al would have a film containing uncured residue of between **500,000 ppb to 15,000,000 ppb** based on emulsifiers present in an amount of between 0.05 to 20%. Accordingly, the composition of the references, individually and when combined, would never meet the FDA requirements of 50 ppb of uncured residue. (Applicants can provide the Office with a Declaration asserting these facts if necessary).

By contrast, Applicants provide data to support and illustrate that films formed from their method of producing low-extractable film by providing an actinic radiation curable homogeneous aqueous composition is compliant with standard food and beverage packaging regulations (see in particular pages 12 to 22 and Examples 8, 9, 10 and 11 of Applicants specification). Thus, Applicant's method produces a low-extractable film having less than 50 ppb of uncured residue.

In view of the foregoing, Applicants kindly ask that the rejection be withdrawn.

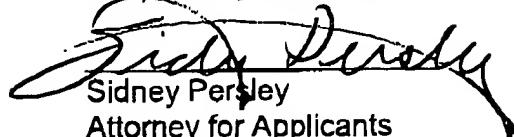
### CONCLUSION

Applicants believe that the Amendments and Remarks provided herein adequately and completely address the rejections raised by the Examiner.

Therefore, Applicants respectfully request allowance and issuance of the outstanding claims.

December 26, 2002

Respectfully submitted,

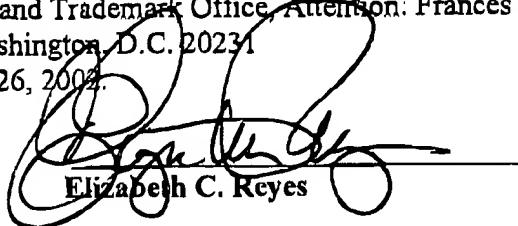


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Elizabeth C. Reyes

## VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

Please amend the paragraph starting at page 2, lines 20-31 and continuing on page 3, lines 1-7, to read as follows:

The invention is a method for producing a low-extractable film (i.e., printing ink film or coating) comprising the steps of:

(a) providing an actinic radiation curable homogeneous aqueous composition [comprising] having a water soluble compound which contains at least one alpha, beta-ethylenically unsaturated, radiation polymerizable group; and water; and

(b) applying said homogeneous aqueous composition onto a surface; and  
(c) irradiating the surface [in a single step] with actinic radiation in the presence of water to form a cured film; wherein less than 50 ppb of uncured residue is extractable from the cured film when said film is immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Please amend the paragraph on page 3, lines 8-16, to read as follows:

A further embodiment of this invention is an improved actinic radiation curable [single fluid] homogeneous aqueous composition [comprising] having a water soluble compound which contains at least one alpha, beta-ethylenically unsaturated, radiation polymerizable group; and water; wherein the improvement comprises the requirement that when a surface is coated with the composition

and exposed [once] to actinic radiation in the presence of water, a cured film is formed wherein less than 50 ppb of uncured residue is extractable from the cured film when immersed and heated in 10 ml of a simulant liquid per square inch of cured film. Preferably, the water soluble compound is a water soluble oligomer containing two or more acrylic groups.

Please amend the paragraph on page 3, lines 17-24, to read as follows:

A still further embodiment of this invention is a packaging material comprising a substrate and a cured film adhered to the surface of the substrate, wherein: the cured film is derived by providing a[n] homogeneous aqueous composition consisting essentially of a water soluble oligomer containing two or more acrylic groups; and water and curing the homogeneous aqueous composition [in a single step] by actinic radiation in the presence of water such that less than 50 ppb of oligomer residue is extractable from the cured film when it is immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

#### In the Claims

Please amend Claim 1 as follows:

1. (Twice Amended) A method for producing a low-extractable film comprising the steps of:  
(a) providing an actinic radiation curable homogeneous aqueous composition [comprising] having:

- (j) a water soluble compound which contains at least one alpha, beta-ethylenically unsaturated, radiation polymerizable group and
- (ii) water;

(b) applying said aqueous composition onto a surface; and

(c) irradiating the surface [in a single step] with actinic radiation in the presence of the water; thereby forming a cured film wherein less than 50 ppb of uncured residue is extractable from the cured film when immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Please amend Claim 27 as follows:

**27. (Twice Amended)** An improved actinic radiation curable [single fluid] homogeneous aqueous composition [comprising] having: a water soluble compound which contains (a) at least one alpha, beta-ethylenically unsaturated, radiation polymerizable group and (b) water; wherein the improvement comprises that when a surface is coated with the composition and exposed [once] to actinic radiation in the presence of the water, a cured film is formed wherein less than 50 ppb of uncured residue is extractable therefrom when immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Please amend Claim 48 to read as follows:

**48. (Twice Amended)** A packaging material comprising a substrate and a cured film adhered to the substrate surface derived by providing a[n] homogeneous aqueous composition consisting essentially of (a) a water soluble oligomer containing two or more acrylic groups and (b) water; applying the

homogeneous aqueous composition on the substrate; and curing [in a single step] by actinic radiation in the presence of the water, such that less than 50 ppb of oligomer residue is extractable from the cured film when immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Please cancel Claims 11, 12, 36, 37, 51 and 52.

Please add Claim 53 as follows:

53. (New) An improved actinic radiation curable printing ink comprising:

(a) a colorant; and

(b) a resin;

wherein the improvement comprises the ink containing an actinic radiation curable homogeneous aqueous composition having: a water soluble compound which contains (a) at least one alpha, beta-ethylenically unsaturated, radiation polymerizable group and (b) water;

Please add Claim 54 as follows:

54. (New) The printing ink composition of Claim 53 wherein when a surface is coated with the actinic radiation curable homogeneous aqueous composition and exposed to actinic radiation in the presence of the water, a cured film is formed wherein less than 50 ppb of uncured residue is extractable therefrom when immersed and heated in 10 ml of a simulant liquid per square inch of cured film.

Please add Claim 55 as follows:

55. (New) The printing ink composition of Claim 53 wherein the colorant is a dye, a pigment or a mixture thereof.